

Amendment and Response  
Serial No.: 10/038,984  
Confirmation No.: 9705  
Filed: January 4, 2003  
For: Li et al.

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### Remarks

The Office Action mailed November 3, 2005 has been received and reviewed. Claim 81 having been added, claims 22, 39, and 75 having been amended, and claim 21 having been canceled, without prejudice, the pending claims are claims 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, 72-76, and 78-81. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim 75 has been amended to recite "explanting a vertebrate cell." It is Applicants' position that this amendment does not narrow the scope of the claims.

New claim 81 does not recite new matter, and finds support, for example, in previous claim 21 of the response filed March 8, 2005, as well as the specification of the application on page 10, line 22.

Applicants appreciate the Examiner's indication that claims 1-7, 15-19, 27-32, 48, 62, 63, 72-74 and 78-80 contain allowable subject matter.

### The 37 CFR §1.75 Objection

The Examiner objected to claim 21 under 37 CFR §1.75 as being a substantial duplicate of claim 1. Applicants further note that an earlier version of claim 21, reciting embryonic fish cells, was present in the response filed March 8, 2005 and had been indicated by the Examiner in the Office Action dated June 14, 2005, as being allowable if rewritten in independent form. Accordingly, Applicant has canceled current claim 21 and added new claim 81 which recreates the version of claim 21 filed March 8, 2005, but rewritten in independent form. Applicants further note that claim 81 is not a substantial duplicate of claim 1, and accordingly respectfully request that the objection under 37 CFR §1.75 be withdrawn.

### The 35 U.S.C. §102 Rejection

The Examiner rejected claims 75 and 76 under 35 U.S.C. §102(e) as being anticipated by Fire et al. (U.S. Patent No. 6,506,559). This rejection is respectfully traversed. Applicants note that these claims were previously indicated as being allowed in the Office Action mailed June 14, 2005, and are disappointed that the Examiner is now rejecting these claims, particularly in

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light of the absence of any subsequent amendment to these claims by Applicants or the introduction of any new art by Applicants or the Examiner.

To anticipate a claim, a single source must contain all of the elements of the claim. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 304, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. See *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716, 223 U.S.P.Q. 1264, 1271 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 U.S.P.Q. 193, 198 (Fed. Cir. 1983).

Claim 75, and dependent claim 76, are directed to a method for attenuating the expression of a target gene in a vertebrate cell *ex vivo*. For convenience and clarity, claim 75 is provided below, with the steps of implanting and explanting indicated in italics for emphasis:

A method for attenuating the expression of a target gene in a vertebrate cell *ex vivo* comprising:

*explanting a vertebrate cell* from a vertebrate organism;  
supplying the cell with a double stranded RNA in an amount sufficient to specifically attenuate expression of the target gene, wherein one of the strands of the double stranded RNA is capable of hybridizing to the target gene in vitro in 400 mM NaCl, 40 mM PIPES pH 6.4, and 1 mM EDTA, at 50°C, and provided that, when the double stranded RNA is supplied to the cell by delivery to the cell of double stranded RNA, the double stranded RNA is formed from single-stranded RNA that is purified in the absence of phenol or chloroform; and  
*implanting the cell* into a vertebrate organism.

This method includes explanting a vertebrate cell from a vertebrate organism and then implanting the cell into a vertebrate organism. Fire et al. does not recite explanting a vertebrate

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cell from a vertebrate organism, and thus Fire et al. does not anticipate all of the elements of claim 75.

In support of the rejection, the Examiner asserts "[e]xplanting a cell from an organism means the method of claim 75 is performed on a cell in vitro." Applicants disagree with this assertion. The Examiner has directed the Applicant to the disclosure of animal cells including vertebrates at column 8, lines 35-51, and the limitation on hybridization conditions at column 7, line 67 to column 8, line 4. However, the Examiner has not indicated where Fire et al. discloses explanting a vertebrate cell from a vertebrate organism, or where Fire et al. discloses implanting the cell into a vertebrate organism. Should the Examiner maintain this rejection, Applicants respectfully request that the Examiner indicate with particularity which portions of Fire et al. describe these steps.

The Examiner also asserts that Fire et al. discloses that the dsRNAs used in the exemplified embodiments were purified without phenol or chloroform. Fire et al. states in column 9, lines 17-22, that "RNA can be purified from a mixture by extraction with a solvent or resin, precipitation, electrophoresis, chromatography, or a combination thereof. Alternatively, the RNA may be used with no or a minimum of purification to avoid losses due to sample processing." Fire et al. does not disclose purification without phenol or chloroform, and thus does not anticipate Applicants' claims 75 and 76.

Applicants respectfully submit that claims 75 and 76 are not anticipated by Fire et al., and respectfully request that the rejection of claims 75 and 76 under 35 U.S.C. §102(e) be withdrawn.

#### **The 35 U.S.C. §112 Rejection**

The Examiner rejected claims 22 and 39 under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. More specifically, the Examiner noted that the claims depend from claims 20 and 23, respectively, which had been canceled. Applicants have

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amended the claims to depend from allowed claim 1, rendering this rejection moot.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112 be withdrawn.

**Summary**

It is respectfully submitted that the pending claims 1-7, 15-19, 22, 27-32, 39, 48, 62, 63, 72-76, and 78-81 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

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February 3, 2006  
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**CERTIFICATE UNDER 37 CFR §1.8:**

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 3 day of February, 2006, at 3:15 pm (Central Time).

By: Sandy TruehartName: SANDY TRUEHART